Docket No.: 21059/0206916-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Bakulesh Khamar et al.

Application No.: 10/565,211 Confirmation No.: 9175

Filed: October 30, 2006 Art Unit: 1645

For: PROCESS FOR MANUFACTURING PHARMACEUTICAL COMPOSITION COMPRISES OF MYCOBACTERIUM W IN THE TREATMENT OF ASTHMA (OBSTRUCTIVE LUNG DISEASE) Examiner: R. P. Swartz

DECLARATION OF DR. BAKULESH KHAMAR UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Dear Sir:

Dr. Bakulesh Khamar, declares under penalty of perjury under the laws of the United States of America as follows:

(1) I have received a M.B.B.S. in 1976 from Gujarat University, Ahmedabad, India. I am currently the Executive Director - Research at Cadila Pharmaceuticals Ltd., where I entered employment in 1996. The assignee of the present application is Rajiv Indravadan Modi, who is the Managing Director of Cadila Pharmaceuticals Ltd. My field of research has been focused on Ophthalmology, Immunology, Metabolic disorder, Gastrointestinal disorder, Novel drug delivery system, Clinical research etc. I have more than 23 peer-reviewed publications in academic journals.

(2) I am the first named inventor on this application. I am familiar with the subject matter and claims of the present application.

(3) I reviewed the Examiner's rejections in the Actions of October 16, 2007 and June 9, 2007. The Examiner rejected Claims 22-48 because the Examiner concluded that "the claimed subject matter was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is most nearly connected, to make and/or use the invention." Specifically, the Examiner required information such as "the actual composition administered to the patients (whole cells, disrupted cells, cell fractions, etc.), the dosage administered, the route of administration, and the frequency of administration." Additionally, the Examiner alleged that some of the amendments to the specification in the response filed 11 June 2007 introduced new matter into the specification.

(4) I reviewed the actual data of the clinical experiments described in the examples in United States Patent Application No. 10/565,211 (the '211 application). In Example 4, the patients were given a Mycobacterium w containing pharmaceutical composition at a dosage of 0.2 ml once per week administered intradermally initially followed by a dosage of 0.1 ml per week administered intradermally once per week. In Example 5, the patients were given a Mycobacterium w containing pharmaceutical composition at a dosage of 0.1 ml administered intradermally once per fortnight. In Example 6, the Mycobacterium w containing pharmaceutical composition was administered via a nebuliser. In Example 7, the patients were given a Mycobacterium w containing pharmaceutical composition at a dosage of 0.1 ml either through intra-dermal or inhalation route at a frequency of one dosage every fortnight. In Example 8, the patients were given a Mycobacterium w containing pharmaceutical composition at a dosage of 0.1 ml.

(5) I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed at Santa Clara, California, United States of America, on this 19 day of December 2007.

Khamar B. M.

Bakulesh Khamar, M.B.B.S.